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BOX PROVISIONAL PATENT APPLICATION
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PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 C.F.R. § 1.53(c).

TITLE: MEDICAL PRESSURE SENSING METHODS AND APPARATUS

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Last	First	MI	City, State or Foreign Country and City

☒ 8 pages of specification are enclosed.

☒ 5 sheets of drawings.

☒ Small entity status is claimed for this application.

☒ Provisional Filing Fee Amount:
☒ $ 80, small entity

☒ A check in the amount of $80.00 to cover the filing fee is enclosed.

☒ The Director is hereby authorized to charge any additional fees which may be required in connection with the filing of this provisional application and recording any assignment filed herewith, or credit over-payment, to Account No. 02-4550. A copy of this sheet is enclosed.

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MEDICAL PRESSURE SENSING METHODS AND APPARATUS

BACKGROUND

A prior art apparatus for precise pressure measurements during manual palpation is described in Zielinski et al., U.S. Patent 5,012,817 and Zielinski et al., Canadian Patent 1,359,224 that are incorporated herein by reference. The apparatus described in these documents uses a thin pressure sensor placed on an examining physician's finger so that the physician retains the sense of touch associated with conventional palpation but in combination with an objective measurement of the applied pressure. The pressure sensor provides an indication of applied pressure based on a resistance change.

This device consists of two parts: (1) a pressure sensor worn on the finger and (2) a separate read-out unit resembling watch and connected to the sensor by a wire. In a typical application, an examining physician or clinician applies a gradually increasing pressure to a selected body part until a patient feels discomfort. The pressure is then released and an optical display shows the value of the pressure associated with the discomfort. The unit then resets itself prior to a subsequent examination.

While this apparatus permits quantification of pressure levels associated with patient discomfort, the clinician must connect the pressure sensor to the read-out unit and keep track of the observed pressures. In addition, pressure read-out requires the clinician to observe the read-out unit directly, removing his attention from the patient. Accordingly, improved apparatus are needed.

DISCLOSURE

Example: Integrated Palpometers

Referring to Figure 1, a palpometer includes a pressure sensor and a liquid crystal display (LCD) or other display or pressure indicator integrated into a unitary device. The palpometer includes a microprocessor having an internal analog-to-digital (A-D) converter configured to digitize a resistance value associated with a force or pressure applied to the pressure sensor, and to provide a digitized value in accordance with a selected pressure scale. The processed, digitized value is then displayed on the LCD. In

some examples, processing of the digitized value is unnecessary, and a digitized value is displayed without processing. In other examples, the A-D converter and the microprocessor are separate circuit components. In other examples, an analog display or other analog read-out is provided, and A-D conversion is unnecessary.

Processing of digitized pressure values can be performed using a series of computer executable instructions stored in a memory such as random access memory (RAM), read-only memory (ROM), flash memory, a memory stick, or other memory types and configurations. A pressure output can also be provided so that pressure values can be delivered to a personal computer, workstation, a patient records database, or to a network or network element such as a server. For example, the device can be configured to transmit stored data to a docking station and eventually to a computer. This transmission can be implemented based on visible, infrared, audio, or electromagnetic transmissions using, for example, an optical transmitter/receiver or a wireless network. Memory can be configured to store one or more pressure values, and the stored values can be delivered after completion of an examination, or measurements can be transmitted during examination. The palpometer can also be configured to receive a patient identification, so that pressure values can be associated with the appropriate patient. While pressure/force sensors based on resistance are convenient, other types of pressure/force sensors could be used, including capacitive, inductive, piezo-electric, and fiber-optic sensors.

A digitized value associated with a sensed pressure/force is produced by the A-D converter, and further processed according to one or more selected pressure scales. For example, a linear pressure or force scale can be used for pressure/force readout. If pressure or force is applied to a fixed area of a pressure sensor, force and pressure are proportional and can be used interchangeably. Force and pressure values can be displayed in units of force-gram (gf) or force-gram per square centimeter (gf/cm^2), respectively. If digitized pressure/force values are based on a linear scale, then the available displayed pressure/force values are separated by a fixed pressure/force increment. While a linear scale can be convenient, linear scales typically do not correspond to human sensory values associated with a stimulus such as pressure or force. Human sensations are generally more accurately described based on a logarithm of the

applied stimulus. For instance, the sensation of a pressure (force) applied to a human body is not proportional to a pressure magnitude but to a logarithm of a pressure magnitude. A logarithmic relationship between an applied stimulus and a sensory response is known as Weber's Law. Such a relationship is known for auditory stimuli in which sensation is proportional to logarithmic units of the sound pressure measured in units called decibels. A logarithmic pressure scale can be divided into various pressure levels, and the resolution can be application-specific. In some applications, only a single pressure value or pressure threshold is used. Sensation of pain is related to pressure rather than force. In almost all examinations even at minimal force the palpating surface area is equal to or greater than the area of the sensor. Nevertheless, sensor readings can be associated with pain sensation even with different examining fingers.

As a particular example of a discrete logarithmic pressure scale, pressure levels are selected such that a given pressure level is equal to a lower pressure level multiplied by a constant. For instance, a discrete five-level logarithmic force scale can have the following levels: 100 gf, 200 gf, 400 gf, 800 gf, and 1600 gf. In this example, each level is twice the previous level. Each force level can have assigned an identification number, such as 1, 2, 3, 4, 5 and/or a name such as very light, light, moderate, strong, very strong. The number of levels in the scale can be varied. In a linear scale the applicable force range is divided into force levels equally separated like: 100 gf, 200 gf, 300 gf, 400 gf, 500 gf or 200 gf, 400 gf, 600 gf, 800 gf, and 1000 gf.. Palpometers can also be configured to use other pressure/force scales. The selection of particular pressure/force scale can be based on clinical needs. For example, one scale may be appropriate for soft tissue examinations while a different scale may be more suitable for examination of joints.

Example: LED and Sonic Palpometers.

Referring to Figure 2, a palpometer can include light emitting diodes (LEDs) configured to indicate sensed pressure/force values instead of or in addition to an LCD. Using a combination of LEDs in "on" and "off" states, a number of LEDs needed for a given measurement resolution can be reduced. For instance, one LED can indicate a

lower or an upper range and an additional three LEDs can indicate a pressure level at a given range. This permits distinguishing up to six levels with only four LEDs.

A representative configuration of LEDs is illustrated in Figure 3. This configuration includes a single red LED and three green LEDs. When the RED level-diode is OFF, the three GREEN indicating diodes indicate force levels 1, 2, or 3. When the RED-level diode is ON (for example, when the RED LED flashing), the GREEN indicating diodes indicate levels 4, 5, or 6. As shown in Figure 3, the level indicated is 4. In other example, separate LEDs are used to indicate different levels. For example, level 1 can be indicated by LED 1, level 2 by LED 2, level 3, by LED 3, level 4 by LED 4, and level 5 by LED 5 as shown in Figure 2.

Optical read-out can be inconvenient, as it requires the clinician to observe the display instead of the patient. In alternative examples, an acoustic indicator can be used in addition to or instead of a display. Pressure values reported by a sensor can be represented as short duration tones (beeps) or using a synthesized human voice. For example, beeps or tones can be generated that are associated with the pressure/force currently being sensed. In a particular example, beeps can be associated with pressure/force values that exceed one or more predetermined levels. The pressure level can be indicated based on, for example, (a) a number of beeps, beeps grouped for ease in counting, (b) beep amplitude and/or duration, (c) beep frequency, based on, for example, a musical scale, (d) a synthesized voice announcing a pressure level, and (e) a combination of any of the above or the like.

An illustrative palpometer with a sonic output is shown in Figure 4. The sonic palpometer includes a piezoelectric speaker or other acoustic transducer in a measurement unit that is configured to be fastened to a finger of an examining clinician with a VELCRO strip, an assembly similar to a watchband, or an elastic material such as a rubber band or a suitable clip. In some examples, the attachment strip can be configured to be consumable and replaced with every examination.

A palpometer can be configured so that an applied pressure on the sensor turns the device "on". After certain duration of inactivity the unit can be configured to turn off or enter a power saving "sleep" mode. Such a configuration lowers part count, cost, and current consumption of the device. The palpometer can be configured to use a very low

current (<1 mA) so that a single battery can provide extended periods of operation and in some examples, the sensor requires replacement or recalibration prior to battery failure. The device can therefore be powered from a non-replaceable battery, and therefore be disposable.

The device can be individually programmed based on the characteristics of the sensor. This eliminates the need to use precision pressure sensors, and lowers device cost. Programming of the device to any pressure/force scale can be a simple procedure that can be performed by the user. For example, exposed electrodes that are provided in the unit can be momentarily shorted to initiate a programming mode followed by application of calibrated pressure levels to the sensor and repeated momentary closures. Such programming enables the use of custom calibration scales, so that the device can be adapted to a particular application.

The operation of a representative sonic palpometer shown in Figure 4 is as follows: The examiner starts an examination by applying very light pressure, and gradually increases the pressure until the patient indicates feeling discomfort. Each time the pressure level exceeds the predetermined level a short beep is generated. Counting these beeps gives the indication of the pressure level reached. As an additional feedback for the examiner, progressive beeps can have increasing frequency with increased pressure, or tones can be arranged on a musical scale. In some applications a certain fixed pressure is applied and a patent is asked if he/she feels discomfort.

Representative circuitry for a sonic palpometer is shown in Figure 7. Sensor resistance decreases with applied pressure from approximately 100 kΩ to 10 kΩ, causing the voltage on the 10 kΩ resistor to rise with applied pressure (certain sensors that can be used have an infinite resistance with no pressure applied.). This voltage is converted to digital form by the micro-controller for further processing. The microcontroller can be programmed to generate an ac voltage that produces a "beep" by a small piezoelectric speaker inside the palpometer. Calibration electrodes are exposed for initiating and for trigging storage of values obtained in a calibration procedure. All the electronics, battery, and the sensor can be provided in a self-contained unit that fits on the clinician's finger.

Calibration can be performed as follows. Two external calibrating electrodes are shorted for about 10 seconds. The micro controller senses this short circuit, and program

code is configured to turn on an analog to digital converter (A-D), a programmable memory, and to put the palpometer in a programmable mode. The sensor is placed in a calibrator and pressure is applied on its sides via bladders or suitable plunger. The sensor's resistance is thereby lowered, which in turn changes the potential seen by the A-D converter. At selected pressure levels, the electrodes are momentarily shorted again and program code initiates the A-D converter to read the input voltage (related to sensor resistance) and store that value in programmable memory as a calibration factor. This factor can be used, for example, as a threshold value at which a beep will sound during the palpometer's regular use. This process is repeated for several pressure settings and the palpometer is then returned to normal operation.

Example: Calibration

Pressure/force sensors typically are calibrated to assure accuracy and the calibration is preferably periodically repeated to assure that the unit is functioning properly. This calibration can be done using pressure or force calibrators. In one example, pressure is applied to the pressure sensor by sandwiching the pressure sensor between two rubber membranes or other compliant sheets. Pressure is applied simultaneously to both membranes allowing for precise calibration of the sensor. Since the sensing surface of the pressure sensor is smaller than the area of the palpating finger, the force exercised by the examining finger can be different for different fingers even with the same pressure as sensed by the pressure sensor. For that reason, for some applications it can be desirable or necessary to calibrate the sensor according to force exercised by a specific examining finger rather than the pressure. This can be accomplished by monitoring of the force applied by the finger on a sensor and by calibrating the palpometer at desired force levels rather than pressure levels.

A force/pressure calibrator can be constructed to automatically calibrate the palpometer to the desired force/pressure levels. This can be done by placing the sensor of a palpometer on a force measuring scale and gradually increasing the force/pressure exercised by the examining finger or by a suitable mechanical plunger pushing the examining finger or by a plunger pushed by a finger and by a mechanical device. The scale's electronic output is continuously monitored by a microprocessor and compared to

the desired calibration points of the palpometer that have been entered previously to the calibrator. Once the desired force level is achieved, the palpometer is automatically calibrated for that level.

Figure 5 is a schematic diagram of an automatic force calibrator for arbitrary measurement scales with arbitrary resolution. The following simple procedure can be used to calibrate the palpometer with the automatic force calibrator to any selected scale:

a) The user places the palpometer in the force calibrator.

b) The user inputs in the number of the thresholds (resolution) and the threshold levels at which he wants the palpometer to signal.

c) The user then starts applying force with the chosen finger until the required require force range is covered as indicated by a suitable acoustic or optical indicator.

d) The calibrator can also allow for "averaging" calibration based on several measurements. If this option is activated, the steps a), b) and c) are repeated several times and the unit is calibrated based on average values obtained during measurements.

An alternative pressure calibration is shown in Figure 6. In use, a sensor is placed between two rubber sheets (membranes) in a bladder chamber that provides space for calibration of six or more sensors. Pressurized air is then pumped into the chamber, squeezing the sensor with the sheets. Pressurized air can be generated manually, as shown in Figure 6, or with a compressor-based pressure regulator. The pressure is measured by an independent pressure gauge.

As noted above, the palpometer can be reprogrammed based on any force/pressure applied to its sensor. Such a force can be applied by an examiner's finger either directly or by a suitable plunger. The pressure level can be arbitrary, as determined by the examiner's "feeling." Alternatively, an external force-measuring device such a scale or force gauge meter can be used to independently measure the force. Once a

desirable level of force is achieved, a corresponding sensor characteristic can be stored in memory by short-circuiting available electric terminals in the palpometer. In such a manner, the entire scale of the palpometer can be calibrated to force exercised by an individual examiner's finger. As the sensor ages, the user can recalibrate as necessary.

This process can be automated in a suitable calibrator. The palpometer is set to a programming mode, and a force is applied gradually by a suitable mechanical device to cover the required range. The force can also be applied by a mechanical device or human finger directly or through suitable plunger. A calibrator can be configured to short-circuit programming terminals each time the pressure reaches a predetermined level, triggering storage. The number of levels and their values can be input to the calibrator prior to the calibration procedures.

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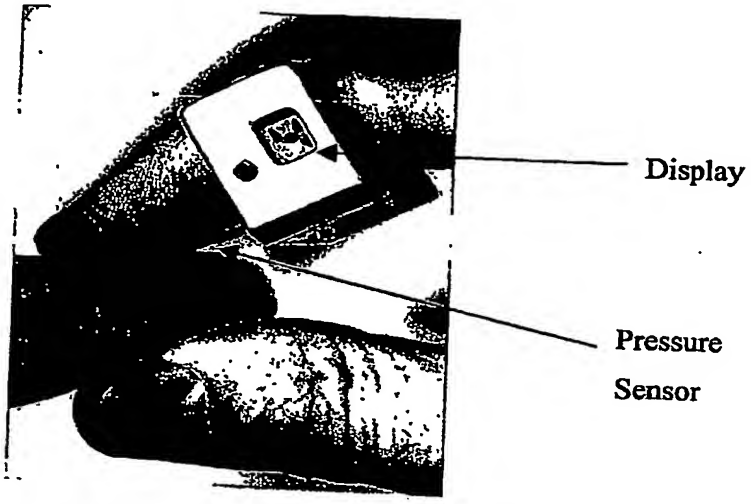

Figure 1. LCD Palpometer

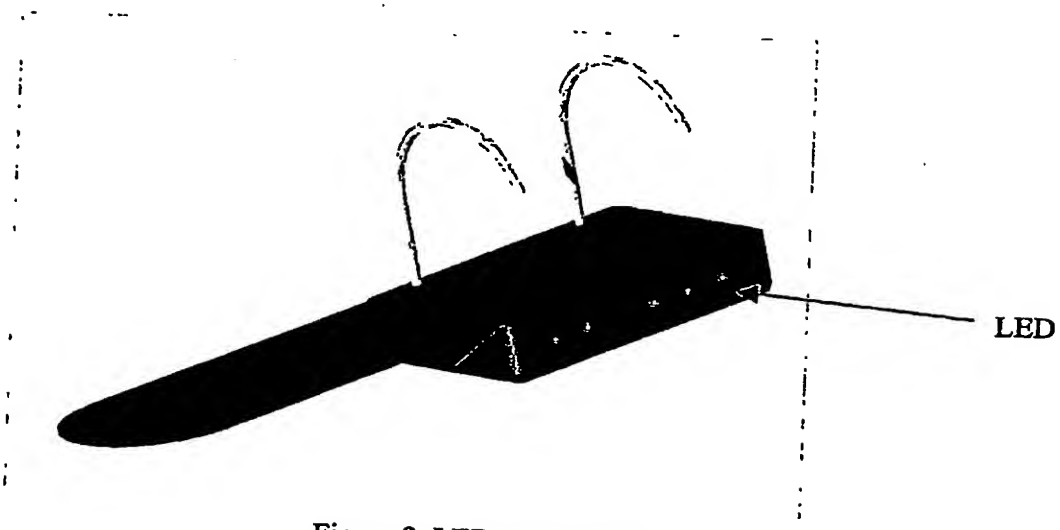

Figure 2. LED Palpometer

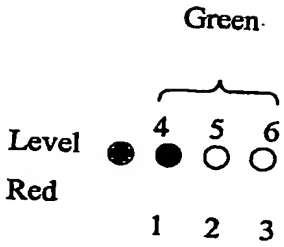

Figure 3. LED Display

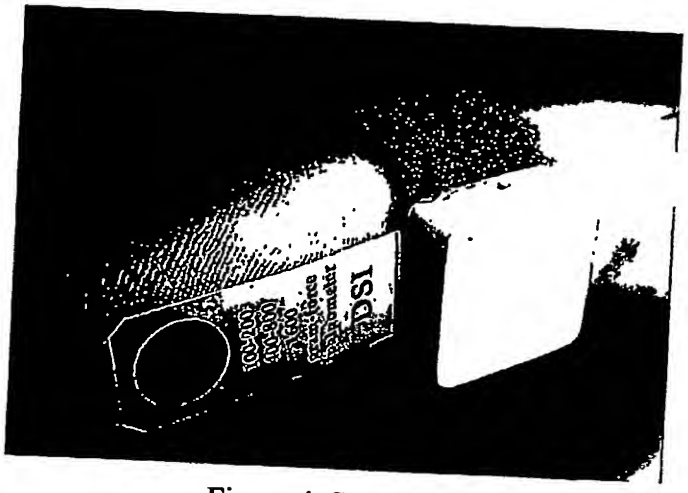

Figure 4. Sonic Palpometer

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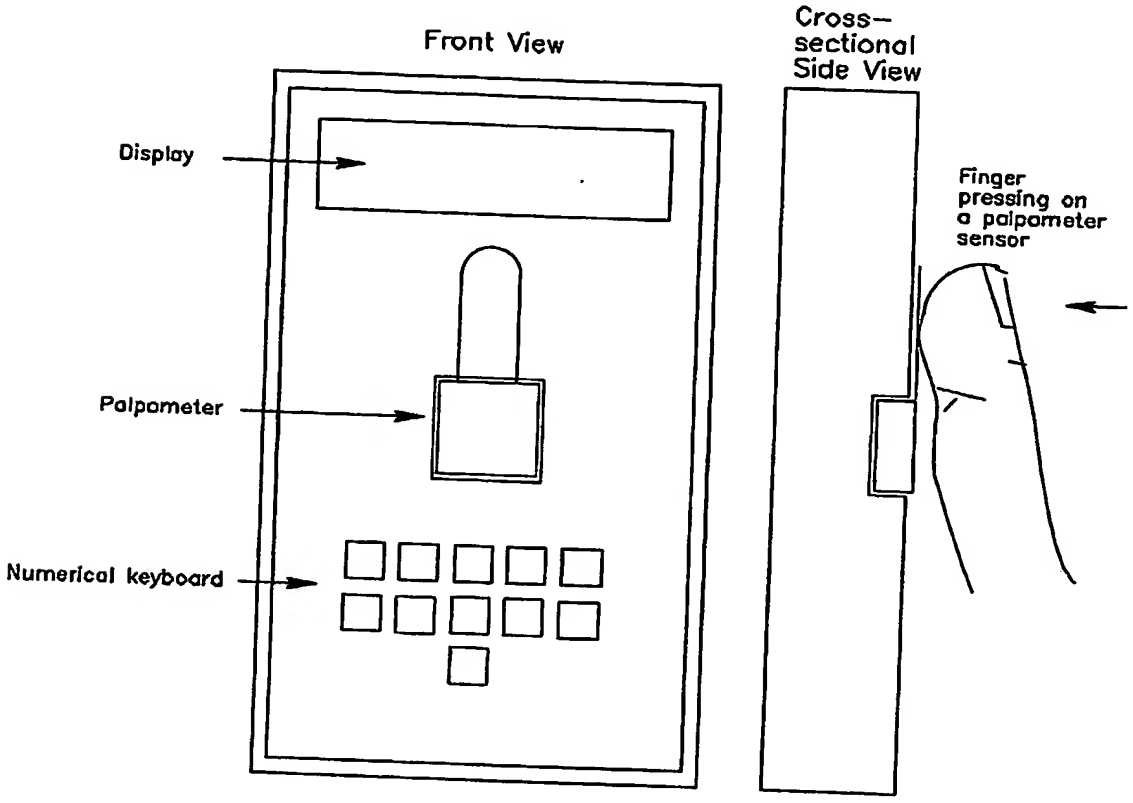
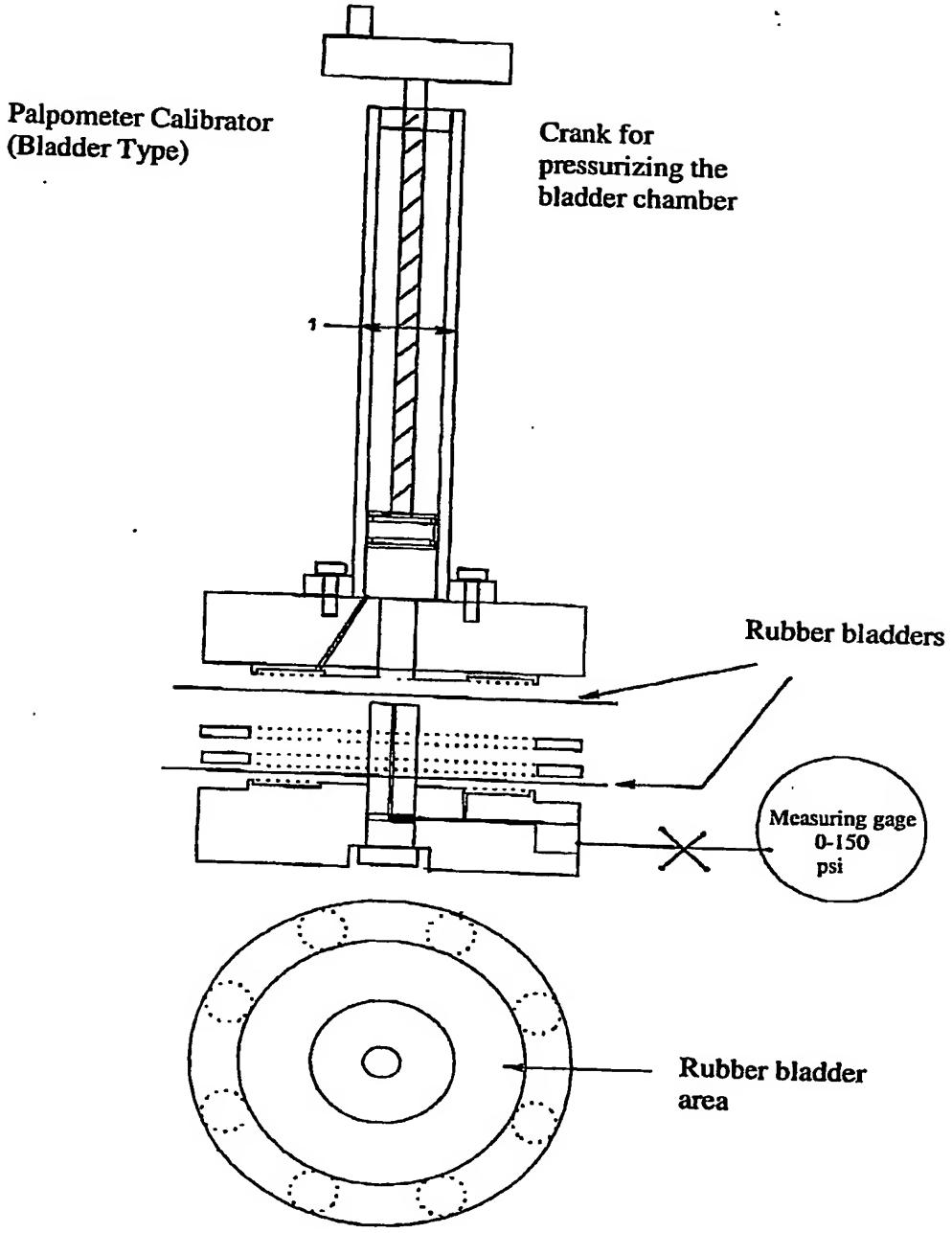


Figure 5. Automatic force calibrator shown with a Palpometer


Palpometer Calibrator
(Bladder Type)
Crank for
pressurizing the
bladder chamber
Rubber bladders
Measuring gage
0-150
psi
Rubber bladder
area

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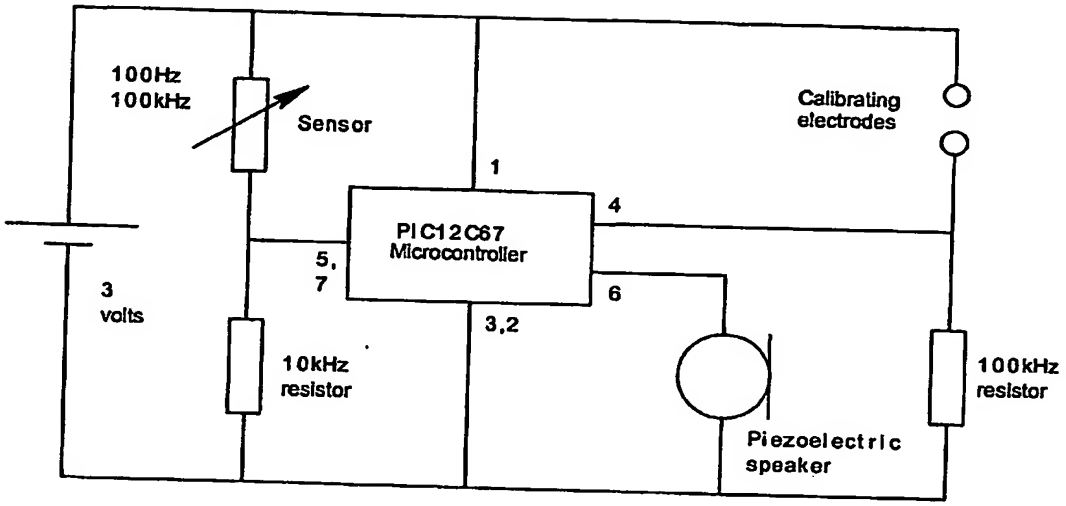

Figure 7. Circuit Diagram of the Palpometer.